during manufacturing and storage is an issue because of spontaneous deamidation. Aswad and coworkers have detailed the deamidation of biologicals (62,63). The stability of proteins can also be compromised by degradation catalyzed by contaminating proteases and by the related issue of aggregation (64,65,66). Proteases can occur as contaminants during the drug-manufacturing process, and proteases also occur in the human body. Polyethylene glycol can be connected to recombinant enzymes and cytokines to enhance the stability and lifetime of the drug in the bloodstream. Polypeptide drugs that are modified in this way are called, pegylated polypeptides (67,68,69), where the polyethylene glycol can be attached to residues of lysine or arginine (70,71,72).

For drugs that are antibodies, enzymes, cytokines, and hormones, what is desired is that the drug not be immunogenic. In striking contrast, for drugs that are vaccines, what is desired and essential, is that the drug stimulate a vigorous immunogenic response. A knowledge of the amino acids is needed for understanding all of the above issues. Undesired immunogenicity arises where the drug takes the form of extract from a tissue or organ from an animal, or where the drug takes the form of a recombinant version of an animal protein. Undesired immunogenicity can be reduced or eliminated by the process of "humanization," where the genetic engineer alters the primary sequence of the animal protein so that it matches the primary sequence of the corresponding human protein (73).

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